Complete Summary

GUIDELINE TITLE

Abnormal vaginal bleeding.

BIBLIOGRAPHIC SOURCE(S)

Fleischer AC, Andreotti RF, Bohm-Velez M, Horrow MM, Hricak H, Javitt MC, Thurmond A, Zelop C, Expert Panel on Women's Imaging. Abnormal vaginal bleeding. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 5 p. [23 references]

GUIDELINE STATUS

This is the current release of the guideline.

The appropriateness criteria are reviewed annually and updated by the panels as needed, depending on introduction of new and highly significant scientific evidence.

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Abnormal vaginal bleeding

GUIDELINE CATEGORY

Diagnosis

CLINICAL SPECIALTY

Family Practice
Internal Medicine
Obstetrics and Gynecology
Radiology

INTENDED USERS

Health Plans
Hospitals
Managed Care Organizations
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

To evaluate the appropriateness of initial radiologic examinations for patients with abnormal vaginal bleeding

TARGET POPULATION

Women with abnormal vaginal bleeding

INTERVENTIONS AND PRACTICES CONSIDERED

1. Ultrasound (US)
    - Uterus, transvaginal (TV)
    - Pelvis, transabdominal (TA)
    - Uterus, hysterosonogram
    - Doppler
2. Magnetic resonance imaging (MRI), pelvis
3. Computed tomography (CT), pelvis

MAJOR OUTCOMES CONSIDERED

Utility of radiologic examinations in differential diagnosis

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The guideline developer performed literature searches of peer-reviewed medical journals and the major applicable articles were identified and collected.

NUMBER OF SOURCE DOCUMENTS

The total number of source documents identified as the result of the literature search is not known.

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Not Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Not stated

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

One or two topic leaders within a panel assume the responsibility of developing an evidence table for each clinical condition, based on analysis of the current literature. These tables serve as a basis for developing a narrative specific to each clinical condition.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus (Delphi)

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Since data available from existing scientific studies are usually insufficient for meta-analysis, broad-based consensus techniques are needed for reaching agreement in the formulation of the appropriateness criteria. The American College of Radiology (ACR) Appropriateness Criteria panels use a modified Delphi technique to arrive at consensus. Serial surveys are conducted by distributing questionnaires to consolidate expert opinions within each panel. These questionnaires are distributed to the participants along with the evidence table and narrative as developed by the topic leader(s). Questionnaires are completed by participants in their own professional setting without influence of the other members. Voting is conducted using a scoring system from 1-9, indicating the least to the most appropriate imaging examination or therapeutic procedure. The survey results are collected, tabulated in anonymous fashion, and redistributed after each round. A maximum of three rounds is conducted and opinions are unified to the highest degree possible. Eighty percent agreement is considered a consensus. This modified Delphi technique enables individual, unbiased expression, is economical, easy to understand, and relatively simple to conduct.

If consensus cannot be reached by the Delphi technique, the panel is convened and group consensus techniques are utilized. The strengths and weaknesses of each test or procedure are discussed and consensus reached whenever possible.

If "No consensus" appears in the rating column, reasons for this decision are added to the comment sections.

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

A formal cost analysis was not performed and published cost analyses were not reviewed.

METHOD OF GUIDELINE VALIDATION

Internal Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Criteria developed by the Expert Panels are reviewed by the American College of Radiology (ACR) Committee on Appropriateness Criteria.

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

ACR Appropriateness Criteria®

Clinical Condition: Abnormal Vaginal Bleeding

Variant 1: Postmenopausal vaginal bleeding.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, uterus, transvaginal (TV)	9	
US, pelvis, transabdominal (TA)	8	
US, uterus, hysterosonogram	6	
US, Doppler	4	
CT, pelvis	2	
MRI, pelvis	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9		

Radiologic Exam Procedure	Appropriateness Rating	Comments
1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 2: Postmenopausal vaginal bleeding, endometrium <5 mm by transvaginal ultrasound.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, pelvis, transabdominal (TA)	4	
US, Doppler	2	
US, uterus, hysterosonogram	2	
CT, pelvis	2	
MRI, pelvis	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 3: Postmenopausal vaginal bleeding, endometrium ≥ 5 mm by transvaginal ultrasound.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, uterus, hysterosonogram	8	
US, pelvis, transabdominal (TA)	4	
US, Doppler	4	
CT, pelvis	2	
MRI, pelvis	2	
Appropriateness Criteria Scale		

Radiologic Exam Procedure	Appropriateness Rating	Comments
1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field

Variant 4: Premenopausal vaginal bleeding.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, uterus, transvaginal (TV)	9	
US, pelvis, transabdominal (TA)	8	
US, uterus, hysterosonogram	4	
US, Doppler	2	
CT, pelvis	2	
MRI, pelvis	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field

Variant 5: Premenopausal vaginal bleeding, endometrium <16 mm by transvaginal ultrasound.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, pelvis, transabdominal (TA)	4	
US, uterus, hysterosonogram	4	Depends on phase of cycle
US, Doppler	2	
CT, pelvis	2	

Radiologic Exam Procedure	Appropriateness Rating	Comments
MRI, pelvis	2	
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Variant 6: Premenopausal vaginal bleeding, endometrium ≥16 mm by transvaginal ultrasound.

Radiologic Exam Procedure	Appropriateness Rating	Comments
US, uterus, hysterosonogram	6	
US, Doppler	4	Depends on phase of cycle
MRI, pelvis	4	
CT, pelvis	2	
US, pelvis, transabdominal (TA)	No consensus	Transabdominal sonography is usually performed at the time of the transvaginal study.
Appropriateness Criteria Scale 1 2 3 4 5 6 7 8 9 1 = Least appropriate 9 = Most appropriate		

Note: Abbreviations used in the tables are listed at the end of the "Major Recommendations" field.

Virtually every woman will at some point in her lifetime experience episodes of vaginal bleeding that will be perceived as abnormal. Menses begin at puberty and extend to menopause. The average menstrual cycle is 29 days long with a range of 23-39 days. Overall, the length of the menstrual cycle remains relatively constant throughout the reproductive years, but as a woman approaches menopause, the cycle gradually shortens. Although blood loss is difficult to quantify, most blood loss occurs in the first few days of menses, and bleeding generally lasts from 2 to 7 days. The cycle length and the volume and duration of bleeding remain fairly constant for a woman throughout her reproductive years. After menopause, bleeding ceases completely. Any variation from this pattern is potentially abnormal.

Abnormal vaginal bleeding is most often caused by hormone imbalance. Vaginal bleeding is also caused by pregnancy, polyps, myomas, endometrial hyperplasia,

adenomyosis and cancers of the cervix or endometrium. In a premenopausal or perimenopausal woman, who is not pregnant, the most likely cause of abnormal bleeding is anovulatory cycles. It may also be associated with adenomyosis in parous women. In a postmenopausal woman, the most likely cause of abnormal bleeding is atrophic endometrium. In either case, a trial of medical hormonal therapy can be instituted. If bleeding persists despite medical management, imaging studies are warranted. In younger women, the goal is to diagnose polyps, myomas, or other focal structural causes for bleeding. In older women the goal is the same and includes diagnosis of endometrial cancer, which is the underlying cause in 10% of postmenopausal women with abnormal bleeding. Meta-analysis has shown that an endometria $\geq$5 mm is associated with less than 1% probability of endometrial cancer.

Transvaginal Ultrasound

Transvaginal ultrasound (TVUS) depicts endometrial pathology. The upper limit of normal for endometrial thickness has been debated. For premenopausal women with bleeding, a thickness of >16 mm has a sensitivity of 67%, specificity of 75%, and positive predictive value of 14% for demonstrating relevant pathology. For postmenopausal women with bleeding, a thickness of >5 mm has a sensitivity of at least 82% for detecting relevant pathology, and for detecting endometrial cancer has a sensitivity of 80%-100% and a specificity of about 60%. Few clinicians advocate mandatory uterine sampling for abnormal postmenopausal bleeding regardless of the ultrasound findings. Most, however, suggest that endometrial sampling is not necessary if thickness is <5 mm. When the endometrium is thickened, the vaginal sonogram helps localize focal lesions, thereby reducing the risk of missing lesions at sampling.

Myometrial pathology causing menorrhagia can be diagnosed by both TVUS and MRI. Although both modalities can be used effectively to diagnose adenomyosis and differentiate it from leiomyomas, TVUS is usually the first imaging study obtained in patients with abnormal bleeding. Using specific criteria, sonography demonstrates a sensitivity of 80%-86% and specificity of 50%-96%.

Hysterosonography

Hysterosonography consists of introduction of saline into the uterine cavity via a small catheter using TVUS guidance. In 48 postmenopausal women with bleeding and endometrial thickness between 5-10 mm, the distension of the cavity with saline revealed focal cavitary masses in 19 (40%). Seven of the patients with endometrial masses had biopsy prior to hysterosonography, and the biopsy was false negative in four (57%). In both premenopausal and postmenopausal women with abnormal bleeding and endometrial thickening, the exclusion of a focal mass may help direct management to hormone treatment or blind biopsy, whereas the identification of a focal mass may direct management to hysteroscopically-guided biopsy.

Transabdominal Ultrasound

Although transabdominal ultrasound gives an overall view of the pelvis, the depiction of the endometrium is better with TVUS. 3D sonography, either

transabdominal or transvaginal, can detect endometrial lesions better than 2D due to depiction of the endometrium in the coronal plane.

Doppler Ultrasound

In postmenopausal women with vaginal bleeding, there is evidence to suggest that the uterine artery resistive index and the pulsatility index are lower for endometrial cancer than for benign lesions. There is, however, variability from institution to institution and overlap between benign and malignant findings. In general, duplex Doppler ultrasound does not add significant additional information to gray-scale imaging of the endometrium. However, color Doppler sonography can identify the feeding vessel of a polyp, significantly aiding their detection.

Magnetic Resonance Imaging

MRI of the pelvis is not warranted unless bleeding is attributed to leiomyomas and myomectomy is contemplated, or sonography is indeterminate in differentiating adenomyosis from leiomyomas. MRI accurately depicts the size, number, and location of leiomyomas. Using specific criteria, MRI differentiates adenomyosis from leiomyomas with a high degree of accuracy.

Computed Tomography

CT scan of the pelvis is not warranted for diagnosis of abnormal vaginal bleeding.

Abbreviations

- CT, computed tomography
- MRI, magnetic resonance imaging
- US, ultrasound

CLINICAL ALGORITHM(S)

Algorithms were not developed from criteria guidelines.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The recommendations are based on analysis of the current literature and expert panel consensus.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

Selection of appropriate radiologic imaging procedures for patients with abnormal vaginal bleeding

POTENTIAL HARMS

Not stated

QUALIFYING STATEMENTS

QUALIFYING STATEMENTS

An American College of Radiology (ACR) Committee on Appropriateness Criteria and its expert panels have developed criteria for determining appropriate imaging examinations for diagnosis and treatment of specified medical condition(s). These criteria are intended to guide radiologists, radiation oncologists, and referring physicians in making decisions regarding radiologic imaging and treatment. Generally, the complexity and severity of a patient's clinical condition should dictate the selection of appropriate imaging procedures or treatments. Only those exams generally used for evaluation of the patient's condition are ranked. Other imaging studies necessary to evaluate other co-existent diseases or other medical consequences of this condition are not considered in this document. The availability of equipment or personnel may influence the selection of appropriate imaging procedures or treatments. Imaging techniques classified as investigational by the U.S. Food and Drug Administration (FDA) have not been considered in developing these criteria; however, study of new equipment and applications should be encouraged. The ultimate decision regarding the appropriateness of any specific radiologic examination or treatment must be made by the referring physician and radiologist in light of all the circumstances presented in an individual examination.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

IMPLEMENTATION TOOLS

Personal Digital Assistant (PDA) Downloads

For information about availability, see the "Availability of Companion Documents" and "Patient Resources" fields below.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Getting Better

IOM DOMAIN

Effectiveness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Fleischer AC, Andreotti RF, Bohm-Velez M, Horrow MM, Hricak H, Javitt MC, Thurmond A, Zelop C, Expert Panel on Women's Imaging. Abnormal vaginal bleeding. [online publication]. Reston (VA): American College of Radiology (ACR); 2006. 5 p. [23 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2006

GUIDELINE DEVELOPER(S)

American College of Radiology - Medical Specialty Society

SOURCE(S) OF FUNDING

The American College of Radiology (ACR) provided the funding and the resources for these ACR Appropriateness Criteria®.

GUIDELINE COMMITTEE

Committee on Appropriateness Criteria, Expert Panel on Women's Imaging

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

Panel Members: Arthur C. Fleischer, MD; Rochelle F. Andreotti, MD; Marcela Böhm-Vélez, MD; Mindy M. Horrow, MD; Hedvig Hricak, MD, PhD; Marcia C. Javitt, MD; Amy Thurmond, MD; Carolyn Zelop, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

Not stated

GUIDELINE STATUS

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GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

ACR Appropriateness Criteria® Anytime, Anywhere™ (PDA application). Available from the ACR Web site.

Print copies: Available from the American College of Radiology, 1891 Preston White Drive, Reston, VA 20191. Telephone: (703) 648-8900.

AVAILABILITY OF COMPANION DOCUMENTS

The following is available:

- ACR Appropriateness Criteria®. Background and development. Reston (VA): American College of Radiology; 2 p. Electronic copies: Available in Portable Document Format (PDF) from the American College of Radiology (ACR) Web site.

PATIENT RESOURCES

None available

NGC STATUS

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